IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: GENERIC PHARMACEUTICALS PRICING ANTITRUSTLITIGATION

MDL 2724 16-MD-2724

HON. CYNTHIA M. RUFE

IN RE: DIVALPROEX ER CASES

16-DV-27240

THIS DOCUMENT RELATES TO:

ALL DIRECT PURCHASER ACTIONS

16-DV-27241

Civil Action No.

KPH HEALTHCARE SERVICES, INC., a/k/a KINNEY DRUGS, INC., individually and on behalf of all others similarly situated

Plaintiffs,

v.

DR. REDDY'S LABORATORIES, INC.;
IMPAX LABORATORIES, INC.; MYLAN,
INC.; MYLAN PHARMACEUTICALS, INC.;
WOCKHARDT, LTD.; MORTON
GROVE PHARMACEUTICALS, INC.;
PAR PHARMACEUTICAL, INC.;
PAR PHARMACEUTICAL COMPANIES, INC.;
AUROBINDO PHARMA USA, INC.; AND
ZYDUS PHARMACEUTICALS (USA), INC.

Jury Trial Demanded

Defendants.

I. INTRODUCTION

1. Plaintiff KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. ("Plaintiff"), brings this Class Action Complaint on behalf of itself and on behalf of a Class of direct purchasers (hereinafter referred to as "Class Members") who purchased generic Divalproex

sodium extended release tablets ("Divalproex ER") from Defendants Dr. Reddy's Laboratories, Inc.; Impax Laboratories, Inc.; Mylan, Inc.; Mylan Pharmaceuticals, Inc.; Wockhardt, Ltd.; Morton Grove Pharmaceuticals, Inc.; Par Pharmaceutical, Inc.; Par Pharmaceutical Companies, Inc.; Aurobindo Pharma USA, Inc.; and Zydus Pharmaceuticals (USA), Inc., during the period from June 2013 to the present (hereinafter referred to as "Class Period").

- 2. Plaintiff seeks to recover damages incurred by itself and the Class due to Defendants' and co-conspirators' violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, by engaging in an overarching scheme to eliminate competition in the market for generic Divalproex ER and to artificially inflate the prices through unlawful agreements.
- 3. As a result of Defendants' anticompetitive scheme, Plaintiff and Class Members paid more for generic Divalproex ER than they otherwise would have paid in the absence of Defendants' unlawful conduct. As set forth below, Defendants' scheme violates the federal antitrust laws and, in particular, Section 1 of the Sherman Act, 15 U.S.C. § 1 ("Sherman Act").
- 4. Plaintiff makes the allegations herein based on personal knowledge and investigation of these matters relating to itself and upon information and belief as to all other matters.

II. NATURE OF THE CASE

5. Defendants have collectively and unlawfully colluded to restrain and/or eliminate competition by engaging in an anticompetitive conspiracy designed to foreclose competition in the market for generic Divalproex ER in the United States, in violation of Section 1 of the Sherman Act. This misconduct enabled each and every Defendant to overcharge direct purchasers for generic Divalproex ER.

- 6. Plaintiff, on behalf of itself and the proposed Class, seeks redress for the overcharge damages sustained as a result of Defendants' unlawful conspiracy and other anticompetitive conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. But for Defendants' illegal conduct, Plaintiff and Class Members would not have paid supracompetitive prices for generic Divalproex ER.
- 7. Plaintiff's allegations made on behalf of itself and Class Members are based on information made public during government investigations of Defendants for alleged unlawful conduct in the generic drug market. In 2014, the U.S. Department of Justice, Antitrust Division ("DOJ") began an in-depth investigation of alleged criminal conduct in the generic drug industry. As a result of the DOJ's investigation, grand jury subpoenas were issued to Defendants Dr. Reddy's, Impax, Mylan, Par, Aurobindo, and Zydus.
 - 8. Generic Divalproex ER is not the only drug at issue in the DOJ's investigation.
- 9. The DOJ's 2014 investigation followed a congressional hearing and investigation prompted by the National Community Pharmacists Association's ("NCPA") January 2014 correspondence to the U.S. Senate Health Education Labor and Pensions ("HELP") Committee and the U.S. House Energy and Commerce Committee requesting hearings on the significant spike in generic drug pricing. The NCPA's news release states,

Pharmacy acquisition prices for many essential generic drugs have risen by as much as 600%, 1,000% or more, according to a survey of more than 1,000 community pharmacists conducted by NCPA. The same survey found that patients are declining their medication due to increased co-pays (or total costs for the uninsured) and that the trend has forced more seniors into Medicare's dreaded coverage gap (or "donut hole") where they must pay far higher out-of-pocket costs.

News release available at http://www.ncpanet.org/newsroom/news-releases/2014/01/08/generic-drug-price-spikes-demand-congressional-hearing-pharmacists-say.

"Over the last six months I have heard from so many of our members across the U.S. who have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate," NCPA CEO B. Douglas Hoey, RPh, MBA wrote in a letter to the panels' respective leaders, Chairman Tom Harkin (D-Iowa) and Ranking Member Lamar Alexander (R-Tenn.) and Chairman Fred Upton (R-Mich.) and Ranking Member Henry Waxman (D-Calif.).

- 10. NCPA's survey of community pharmacists found the following:
 - 77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price.
 - 86% of pharmacists said it took the pharmacy benefit manager (PBM) or other third-party payer between two and six months to update its reimbursement rate (but not retroactively).
 - Patients may be referred to other pharmacies because the community pharmacy could not absorb losses of \$40, \$60, \$100 or more per prescription filled, due to inadequate and/or outdated reimbursement rates.
 - 84% of pharmacists said the unsustainable losses per prescription are having a "very significant" impact on their ability to remain in business to continue serving patients.
- 11. In December 2016, the DOJ filed the first criminal indictments to result from the ongoing investigation of the generic drug industry. On December 12 and December 13, 2016, the DOJ filed separate two-count felony indictments in the U.S. District Court for the Eastern District of Pennsylvania against two former executives of Heritage Pharmaceuticals, Inc. for conspiring to allocate customers and fix the prices of two other generic drugs, doxycycline hyclate and glyburide.
- 12. State Attorneys General are also conducting ongoing investigations of the generic drug industry. On December 15, 2016, Connecticut Attorney General George Jepsen, along with the Attorney Generals of nineteen other states, filed suit in the U.S. District Court for the District

 $^{^2}$ See U.S. v. Glazer, 2:16-cr-00506-RBS (E.D. Pa.) and U.S. v. Malek, 2:16-cr-00508-RBS (E.D. Pa.).

of Connecticut against Aurobindo Pharma USA, Inc., Citron Pharma, LLC, Heritage Pharmaceuticals, Inc., Mayne Pharma (USA), Inc., Mylan Pharmaceuticals, Inc., and Teva Pharmaceuticals USA, Inc., for price-fixing of doxycycline hyclate delayed release and glyburide ("the AG Complaint").³ The AG Complaint states claims under Section 1 of the Sherman Act, 15 U.S. C. § 1, and notes that, "the Plaintiff States have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time." Twenty additional states have since joined.

13. Plaintiff reserves the right to amend its complaint to include additional parties and claims related to the pricing of other generic drugs as new information from the government investigations becomes public.

III. JURISDICTION AND VENUE

- 14. This Court has jurisdiction over the subject matter of this action as it arises under Section 1 of the Sherman Act, 15 U.S.C. § 1, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15, 26. Further, this Court has jurisdiction under 28 U.S.C. §§ 1331, 1337(a).
- 15. Venue is proper in this District pursuant to 15 U.S.C. §§ 15 and 22 and 28 U.S.C. § 1391(b) and (c) because during the Class Period, the Defendants transacted business in the United States, including in this District.
- 16. During the Class Period, Defendants sold and shipped generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of generic Divalproex ER in the United States, including in this District. Defendants' conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce in the United States, including in this District.

³ See Connecticut et al. v. Aurobindo Pharma USA, Inc. et al, 3:16-cv-02056-VLB (D. Conn.).

Defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of generic Divalproex ER throughout the United States, including in this District; (c) had and maintained substantial contacts with the United States, including in this District; (d) was engaged in an unlawful conspiracy to inflate the prices for generic Divalproex ER that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

IV. THE PARTIES

A. PLAINTIFF

Plaintiff KPH Healthcare Services, Inc. a/k/a Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH directly purchased generic Divalproex ER from Defendants during the Class Period. For example, KPH's purchases from Defendants during the Class Period include Divalproex ER 250 MG 100 Tabs from Defendant Dr. Reddy's Laboratories. As a result of Defendants' antitrust conspiracy, KPH paid supracompetitive prices for its generic Divalproex ER purchases and KPH was injured by the illegal conduct alleged herein.

B. DEFENDANTS

19. Defendant Dr. Reddy's Laboratories, Inc. ("Dr. Reddy's") is a New Jersey corporation with its principal place of business at 107 College Road East, Princeton, New Jersey, 08540. Dr. Reddy's manufactures, markets, and sells generic drug products. Dr. Reddy's received approval to market generic versions of Divalproex ER in March 2012. During the Class

Period, Dr. Reddy's sold generic Divalproex ER to purchasers in this District and throughout the United States.

- 20. Defendant Impax laboratories, Inc. ("Impax") is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. Impax manufactures, markets, and sells generic drug products. Impax received approval to market generic versions of Divalproex ER in May 2009. During the Class Period, Impax sold generic Divalproex ER to purchasers in this District and throughout the United States.
- Defendant Mylan, Inc. is a Pennsylvania corporation with its principal place of business at 100 Mylan Blvd., Canonsburg, Pennsylvania 15317. Defendant Mylan Pharmaceuticals, Inc. is a West Virginia corporation with its principal place of business at 781 Chesnut Ridge Road, Morgantown, West Virginia 26505. In this Complaint, the Mylan Defendants are collectively referred to as "Mylan." Mylan manufactures, markets, and sells generic drug products. Mylan received approval to market generic versions of Divalproex ER in January 2009. During the Class Period, Mylan sold generic Divalproex ER to purchasers in this District and throughout the United States.
- 22. Defendant Par Pharmaceuticals, Inc. is a New York corporation with its principal place of business at One Ram Ridge Road, Chesnut Ridge, New York 10977. Defendant Par Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business at One Ram Ridge Road, Chesnut Ridge, New York 10977. In this Complaint, the Par Defendants are collectively referred to as "Par." Par manufactures, markets, and sells generic drug products. Par's predecessor-in-interest, Anchen Pharmaceuticals, received approval to market generic versions of Divalproex ER in March 2009. During the Class Period, Par sold generic Divalproex ER to purchasers in this District and throughout the United States.

- 23. Defendant Wockhardt, Ltd. is an international corporation operating in the United States with its principal place of business at Wockhardt Towers, Bankra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400051, India. Defendant Morton Grove Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business at 6451 main Street, Morton Grove, Illinois 60053. Defendant Morton Grove Pharmaceuticals, Inc. is a wholly-owned subsidiary of Wockhardt. In this Complaint, the Wockhardt and Morton Grove Defendants are collectively referred to as "Morton Grove." Morton Grove manufactures, markets, and sells generic drug products. During the Class Period, Morton Grove sold generic Divalproex ER to purchasers in this District and throughout the United States.
- 24. Defendant Aurobindo Pharma USA, Inc. ("Aurobindo") is a Delaware corporation with its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Aurobindo manufactures, markets, and sells generic drug products. During the Class Period, Aurobindo sold generic Divalproex ER to purchasers in this District and throughout the United States.
- 25. Defendant Zydus Pharmaceuticals (USA) Inc. ("Zydus") is a New Jersey corporation with its principal place of business at 73 Route 31 N, Pennington, New Jersey 08534. Zydus manufactures, markets, and sells generic drug products. Zydus received approval to market generic versions of Divalproex ER in February 2009. During the Class Period, Zydus sold generic Divalproex ER to purchasers in this District and throughout the United States.
- 26. Defendants have engaged in the conduct alleged in this Complaint, and/or the Defendants' officers, agents, employees, or representatives have engaged in the alleged conduct while actively involved in the management of Defendants' business and affairs.

V. UNIDENTIFIED CO-CONSPIRATORS

- 27. Various other persons, firms, entities and corporations, not named as Defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged herein, and have aided, abetted and performed acts and made statements in furtherance of the conspiracy.
- 28. The true names and capacities, whether individual, corporate, associate, or representative, is unknown to Plaintiff at this time. Plaintiff may amend this Complaint, as necessary, to allege the true names and capacities of additional co-conspirators as their identities become known through discovery.
- 29. At all relevant times, other persons, firms, and corporations, referred to herein as "co-conspirators," the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful monopolization as described herein.
- 30. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

VI. FACTUAL ALLEGATIONS

A. Overview of Generic Drug Market

31. Generic drugs typically provide consumers with a lower-cost alternative to brand name drugs while providing the same treatment. Specifically,

A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug

products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.⁴

- 32. Further, "[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product."⁵
- 33. Generic versions of brand name drugs are priced significantly below the brand name versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand name counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand name product unless the doctor has indicated that the prescription for the brand name product must be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act (Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b; 21 U.S.C. §§ 301 note, 355, 360cc; 28 U.S.C. § 2201; 35 U.S.C. §§ 156, 271, 282)).
- 34. Economic literature in the healthcare market has demonstrated that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand name drug commands 100% of the market share for that drug and the brand name manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the market, however, a brand name drug rapidly loses sales, as much as 80% or more by the end of the first year. As more generic manufacturers enter the market, prices for generic versions of a drug predictably will continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand name drug to the

⁴ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#G

⁵ *Id*.

corresponding generic accelerates as more generic options are available to purchasers.⁶ Generic drugs that are substitutable for a brand name drug become like any other commodity, because the products are interchangeable, competition between the manufacturers is based on price.

- 35. Generic competition usually enables purchasers to (a) purchase generic versions of the brand name drug at a substantially lower price than the brand name drug, and/or (b) purchase the brand name drug at a reduced price. Generic competition to a single branded drug product can result in billions of dollars in savings to consumers, insurers, and other drug purchasers.
- Abbreviated New Drug Application ("ANDA") with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs. The filing is called "abbreviated" because the ANDA sponsor references data submitted in the approval of the Reference Listed Drug ("RLD") (the brand name drug). "By designating a single reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterpart." An ANDA sponsor is generally not required to include clinical trial data to establish the safety and efficacy of the drug. Instead, a generic drug company must show that its generic product is "bioequivalent" to the name brand drug, 8 i.e., the generic product and the brand RLD have the same (i) active ingredient, (ii) maximum amount of drug in the blood at a given time, (iii) total amount of drug

⁶ See, e.g., Ernst R. Berndt, et al., Authorized Generic Drugs, Price Competition, And Consumers' Welfare, Health Affairs 26, no. 3 (2007):790-799.

⁷ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#RLD.

⁸ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#A.

in the blood over time, (iv) strength, dosage, dosage form, (v) expected safety and efficacy, and (vi) FDA approval of manufacturing facilities. Upon the FDA's determination that bioequivalence has been established, the ANDA applicant may manufacture and market its generic drug in the U.S. as interchangeable with the RLD.

37. Generic drugs that are bioequivalent to an RLD are assigned a Therapeutic Equivalence Code ("TE Code"). ⁹ An oral generic drug product will be coded "AB" if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA's evaluations. ¹⁰

B. Consolidation in the Generic Drug Industry

- 38. Since 2005, consolidations in the generic drug industry have affected control of product supply and pricing for consumers.
- 39. For example, Teva Pharmaceutical Industries Ltd. acquired Ivax Corporation for \$7.4 billion in 2006; Barr Laboratories for \$7.4 billion in 2008; Ratiopharm, Germany's second largest generic drug producer, for \$5 billion in 2010, and agreed to acquire Allergan Generics in 2015 for \$40.5 billion. Watson Pharmaceuticals acquired Andrx Corporation in 2006 for \$1.9 billion; Daiichi Sankyo acquired a majority stake in Ranbaxy in 2008; and Endo Pharmaceuticals acquired Qualitest for \$1.2 billion in 2010.
- 40. Consolidation in the generic drug industry has led to higher prices for consumers and the combining or discontinuation of generic product lines, which contributed to reducing price competition. Mergers within the generic drug industry were a reaction, in part, to the

⁹ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#T.

¹⁰ http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm.

consolidation of distributors. Generic manufacturers then had leverage to charge higher prices if distributors were unable to negotiate lower prices with other generic manufacturers offering therapeutically equivalent drugs.

C. Opportunities for Collusion

- 41. The DOJ is reportedly examining trade associations where Defendants allegedly have opportunities to communicate and collude, such as the Generic Pharmaceutical Association's ("GPhA"). According to an intelligence report from the *Policy and Regulatory Report* ("PaRR"), a source that was given inside information by someone with knowledge of the government's generic pricing investigation, the DOJ is looking closely "at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."¹¹
- 42. The GPhA is the "leading trade association for generic drug manufacturers and distributors, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry." GPhA was formed in 2000 from the merger of three industry trade associations: GPhA, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.¹²
 - 43. Defendant Mylan has representatives on GPhA's 2016 Board of Directors.
- 44. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." GPhA states that,

http://www.fiercepharma.com/story/actavis-gets-subpoena-doj-probe-generic-pricing-moves-food-chain/2015-08-07.

¹² In February 2017, the GPhA changed its name to the Association for Accessible Medicines ("AAM"). See Russell Redman, New name for Generic Pharmaceutical Association, CHAIN DRUG REVIEW (Feb. 14, 2017), available at http://www.chaindrugreview.com/new-name-forgeneric-pharmaceutical-association/.

"[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections." ¹³

- 45. Generic drug manufacturers attend meetings and industry trade shows throughout the year, including those hosted by the GPhA, National Association of Chain Drug Stores, Healthcare Distribution Management Association (now the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing.¹⁴
- 46. At these meetings and trade shows, generic drug manufacturers have opportunities to discuss and share competitively sensitive information, such as pricing, upcoming bids, and customer contracts.¹⁵
- 47. Many of these conferences and trade shows also include organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities that provide further opportunity to meet with competitors.
- 48. High-level executives of generic drug manufacturers meet periodically at industry dinners. For example, in January 2014, when certain generic drug prices were increasing exponentially, at least thirteen (13) high-ranking male executives of various generic drug manufacturers met at a steakhouse in Bridgewater, New Jersey.¹⁶

¹³ http://www.gphaonline.org/about/membership.

¹⁴ See AG Complaint at ¶ 50.

¹⁵ *Id.* at ¶ 51.

¹⁶ *Id.* at ¶ 55.

- 49. Female sales representatives for generic drug manufacturers regularly hold meetings and dinners for "Girls Night Out" ("GNO") and Women in the Industry events, where competitively sensitive information is discussed.¹⁷ For example, GNOs were held at the ECRM conference in February 2015, in Baltimore in May 2015, and at the NACDS conference in August 2015.¹⁸
- 50. Several of the generic drug manufacturers, including [#] of the Defendants, have offices in close proximity to one another in New Jersey, eastern Pennsylvania, or New York, providing them with more opportunities to meet and collude.

D. Generic Divalproex ER Market and Pricing Information

- 51. Generic Divalproex ER is an anticonvulsant prescribed for the treatment of migraines and seizures, and its base compound, valproate, has been designated an essential medicine by the World Health Organization.
- 52. Divalproex ER is not a new compound. The essential ingredient from which Divalproex ER is derived, valproate, has been known since the late 19th century.
- 53. AbbVie manufactures and sells a branded version of Divalproex ER under the name Depakote ER. AbbVie's predecessor-in-interest, Abbott Laboratories, submitted NDA 21-168 for the approval of Depakote ER on September 30, 1999. The FDA approved Depakote ER on August 4, 2000, and Abbott Laboratories began selling the drug soon thereafter. Depakote ER was a blockbuster drug for AbbVie, generating over \$900 million in sales.
- 54. Generic versions of Divalproex ER have been on the market for years and, for most of that time, have been priced significantly lower than the branded counterpart. This is

¹⁷ *Id.* at ¶ 57.

¹⁸ *Id.* at ¶ 60.

because the presence of multiple competing versions of generic drugs usually results in vigorous price competition, benefiting direct purchasers and consumers through lower prices.

- 55. Defendants dominate the market for the generic forms of Divalproex ER at issue here.
- 56. However, recently the price of Divalproex ER has experienced unusual and unprecedented price increases. For example, between the middle of 2013 and the middle of 2014, the price of Divalproex ER 500 mg increased over 900%. An August 2016 United States Government Accountability Office ("GAO") Study noted that Divalproex ER has experienced "extraordinary price increases" between 2010 and 2015. 19
- 57. As part of their conspiracy, Defendants agreed to raise the prices of Divalproex ER sold in the United States. Between September 2013 and April2 014, prices of Divalproex ER have risen from \$31 to \$234. One Kansas City pharmacy complained that while a 500-unit bottle of Divalproex ER cost \$122.99 in May 2013, that same bottle cost \$1,629.95 by August 2013.²⁰
- 58. Defendants substantially increased the price of Divalproex ER in unison as a result of an agreement among Defendants to increase pricing and restrain competition for the sale of Divalproex ER in the U.S. The price hikes have not been the result of competitive market forces. Instead the price hikes were the result of Defendants' conspiracy to fix, raise, maintain and stabilize the prices of, and/or allocate customers and markets and rig bids for, Divalproex ER. The price increases were neither the product of a competitive market, nor made necessary by

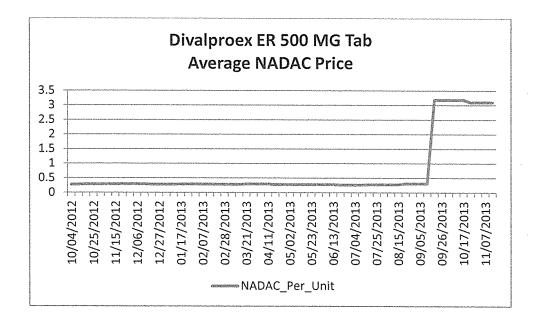
¹⁹ GAO, Report to Congressional Requesters, Generic Drugs Under Medicare: Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases (Aug. 2016), available athttp://www.gao.gov/products/GAO-16-706.

²⁰ Rob Low, Rising cost of some generic drugs set to shock consumers, Fox4 (Aug. 14, 2013), available at http://fox4kc.com/2013/08/14/rising-cost-some-of-generic-drugs-set-toshock-consumers/.

any increased manufacturing costs. And because generic pharmaceutical manufacturers do not need to incur the research and development costs that brand manufacturers invest to develop new prescription drugs, Defendants' price increases cannot be attributed to the need to fund research and development. Defendants' price increases resulted from their conspiracy to restrain trade.

- 59. As a result of Defendants' scheme to fix, raise, maintain, and stabilize the prices of Divalproex ER, direct purchasers such as Plaintiff KPH, have paid and continue to pay supracompetitive prices.
- 60. All of the Defendants are current members of the GPhA. Several of Defendants' high-ranking corporate officers also serve on GPhA's Board of Directors, including Mylan's Heather Bresch, Impax's Marcy Macdonald, Par's Tony Pera, Dr. Reddy's Alok Sonig, and Zydus' Joseph Remner. Ms. Bresch serves as the GPhA's current chair.
- 61. As reflected in price data developed by the National Association of State Medicaid Directors (National Average Drug Acquisition Cost, "NADAC"), prices for Divalproex ER 500 mg increased over 930% from an average market price of \$0.31 per tablet as of September 12, 2013 to \$3.18 per tablet as of September 19, 2013. "NADAC is designed to create a national benchmark that is reflective of the prices paid by retail community pharmacies to acquire prescription and over-the-counter covered outpatient drugs."²¹
- 62. The chart below based upon the NADAC data shows the average price per unit (tablet) of Divalproex ER 500 mg between October 2012 and November 2013.

²¹See https://www.medicaid.gov/Medicaid-CHIP-Program-Information/ByTopics/Benefits/Prescription-Drugs/FUL-NADAC-Downloads/NADACMethodology.pdf.



- 63. Similarly large price increases, in excess of 500% were found for different package sizes of Divalproex ER 250 mg and 500 mg tablets, as noted by Congress in their letters to various generic drug manufacturers.
- 64. Additionally, the NADAC data shows a price increase over 560% for Divalproex ER 250 mg tablets in September 2013.
- 65. Prices for generic Divalproex ER increased without justification and in a departure from the usual industry practices. The cost or availability of raw materials does not justify the price increase. As generic manufacturers, Defendants did not incur the same costs, such as research and development, as brand drug manufacturers in bringing their generic Divalproex ER products to market. The increased prices were not associated with any related increase in manufacturing costs.

- 66. At all times during the class period, there were at least three or more separate manufacturers of generic Divalproex ER. The active ingredient for the drug product, Divalproex sodium, has 13 approved holders of active Drug Master Files ("DMF").²²
- 67. At the time Divalproex ER prices rose in or around the last quarter of 2013, there were no known raw material shortages that would have constrained Defendants' ability to supply the market.
- 68. Under the well-accepted economics of generic competition, when there are that many generic versions of a drug available, all of which by definition are equally substitutable, prices should remain at highly competitive, historic levels, and would not increase as they did here, absent anticompetitive conduct.
- 69. Because there were no justifications such as supply shortages attributable to higher raw material costs, raw material shortages, or manufacturing bottlenecks (such as too few manufacturers to satisfy demand), competition among generic manufacturers of Divalproex ER should have resulted in lower prices. Instead, prices increased after the Defendants met and unlawfully colluded to raise prices.

E. Government Investigations of Generic Drug Industry

70. As noted above, Defendants' conduct in generic pharmaceutical pricing is the subject of federal government investigations by the U.S. Senate and DOJ, as well as state government investigations.

A Drug Master File, or DMF, is a regulatory document that contains the complete information for an active pharmaceutical ingredient (or API or drug substance), or a finished dosage form (the complete drug product, such as a tablet). The DMF contains information on the drug manufacture, stability, purity, chemistry, packaging and the good manufacturing practices that were used in the processes to make the product that is the subject of the DMF.

- 71. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Representative Elijah E. Cummings sent letters to fourteen drug manufacturers, including Defendants Dr. Reddy's, Mylan, Par and Zydus, seeking information relating to the escalating prices of generic drugs (the "October Letters") and raising concerns about the extraordinary price increases Divalproex ER has experienced since 2013.
- 72. The October Letters to Defendants Dr. Reddy's, Mylan, Par and Zydus, state the following:

This dramatic increase in generic prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays..."²³

- 73. The October Letters to Defendants Dr. Reddy's, Mylan, Par and Zydus, requested documents and information from 2012 to the present, including,
 - (1) total gross revenues from the companies' sales of these drugs;
 - (2) the dates, quantities, purchasers and prices paid for all sales of these drugs;
 - (3) total expenses relating to the sales of these drugs, as well as the specific amounts for manufacturing, marketing and advertising, and purchases of active pharmaceutical ingredients, if applicable;
 - (4) sales contracts or purchase agreements for active pharmaceutical ingredients for these drugs, including any agreements relating to exclusivity, if applicable;

²³ See Letter from Senator Sanders and Representative Cummings to Heather Bresch, CEO, Mylan, Inc., October 2, 2014, available at https://www.sanders.senate.gov/download/letter-to-mrs-bresch-ceo-mylan-inc?inline=file.

- (5) a description and valuation of the specific financial and non-financial factors that contributed to your company's decisions to increase the prices of these drugs;
- (6) any cost estimates, profit projections, or other analyses relating to the company's current and future sales of these drugs;
- (7) prices of these drugs in all foreign countries or markets, including price information for the countries paying the highest and lowest prices; and
- (8) the identity of company official(s) responsible for setting the price of these drugs over the above time period.²⁴
- 74. The October Letters were accompanied by a press release by Senator Sanders and Congressman Cummings, which stated,

"We are conducting an investigation into the recent staggering price increases for generic drugs used to treat everything from common medical conditions to life-threatening illnesses," Sanders, chairman of a Senate health care subcommittee, and Cummings, ranking member of the House oversight committee, wrote in letters to 14 pharmaceutical companies.

. . .

Cummings and Sanders cited a survey that found pharmacies across the country "have seen huge upswings in generic drug prices that are hurting patients" and having a "very significant" impact on pharmacists' ability to continue serving patients. The study for the National Community Pharmacists Association also found some patients refused to fill needed prescriptions because of rising prices.

"It is unacceptable that Americans pay, by far, the highest prices in the world for prescription drugs. Generic drugs were meant to help make medications affordable for the millions of Americans who rely on prescriptions to manage their health needs. We've got to get to the bottom of these enormous price increases," Sanders said.

"When you see how much the prices of these drugs have increased just over the past year, it's staggering, and we want to know why," said Cummings. "I am very pleased that Chairman Sanders has joined me in this bicameral investigation

²⁴ *Id.* at page 3.

because in some cases these outrageous price hikes are preventing patients from getting the drugs they need."²⁵

- 75. The U.S. Senate HELP Committee held a hearing on November 20, 2014, "Why Are Some Generic Drugs Skyrocketing in Price?"²⁶
- 76. During the Senate Hearing on generic drug prices, pharmacist Rob Frankil testified on November 20, 2014 that, "it was extremely concerning when about a year ago, pharmacies began noticing a rash of dramatic price increases for many common, previously low-cost generic drugs." Divalproex ER was cited as one of the drugs with a sudden price increase, which impacted patients' ability to afford the drug and pharmacies' ability to operate their businesses.
- 77. On February 24, 2015, Senator Sanders and Congressman Cummings sent a letter to the Office of the Inspector General ("OIG") of the Department of Health and Human Services asking that the OIG "examine recent increases in the prices being charged for generic drugs and the effect these price increases have had on generic drug spending within the Medicare and Medicaid programs." The OIG responded to the request on April 13, 2015 and stated that it planned to review quarterly average manufacturer prices ["AMPs"] for the top 200 generic drugs from 2005 through 2014, and would "determine the extent to which the quarterly AMPs

²⁵ Press release, Congress Investigating Why Generic Drug Prices are Skyrocketing, Oct. 2, 2014, available at http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.

http://www.sanders.senate.gov/newsroom/press-releases/drugmakers-mum-on-huge-price-hikes.

²⁷ http://www.help.senate.gov/imo/media/doc/Frankil.pdf.

²⁸ http://www.sanders.senate.gov/download/sanders-cummings-letter?inline=file.

exceeded the specified inflation factor."²⁹ The OIG concluded that escalating generic drug prices have cost taxpayers \$1.4 billion in overpayment by Medicaid.³⁰ In a 2015 budget deal by Congress, legislation requires generic drug manufacturers to pay back the Medicaid program when their prices rise faster than inflation. Later in 2015, Senator Sanders and Representative Cummings proposed comprehensive legislation to address prescription drugs prices.

- 78. Subsequent congressional hearings concerning the dramatic rise of generic pharmaceutical prices were held in December 2015 and February 2016. At the U.S. Senate Special Committee on Aging's December 9, 2015 hearing, Erin D. Fox, the Director of the Drug Information Service of the University of Utah, noted the deleterious effect these drug prices have had on patient access and healthcare, stating that "[w]hen medication prices increase in an unpredictable and dramatic way, this can create an access issue for hospitals and patients. If hospitals cannot afford to stock a product in the same amount due to price increases, this effectively creates a shortage."
- 79. The DOJ is conducting an ongoing investigation into generic drug pricing. Several leading generic drug manufacturers have been subpoenaed for information, documents and testimony relating to "communication or correspondence with any competitor in the sale of generic prescription medications." Grand jury subpoenas have been issued to at least four of the Defendants. Dr. Reddy's, Mylan, Impax, and Par have been subpoenaed by the DOJ's grand

²⁹ http://www.sanders.senate.gov/download/oig-letter-to-sen-sanders-4-13-2015?inline=file.

³⁰ Office of the Inspector General, Average Manufacture Prices increased faster than Inflation for Many Generic Drugs, December 2015, available at https://oig.hhs.gov/oas/reports/region6/61500030.pdf.

³¹ See Impax Laboratories, Inc., Form 8-K, November 3, 2014.

jury in this District as part of its ongoing investigation of anticompetitive practices in the generic pharmaceutical industry.

that they have potentially violated antitrust law. According to the DOJ's *Antitrust Division Manual*, "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution." If a grand jury request memorandum is approved by the DOJ field office chief, "a grand jury request should be emailed to the ATR-CRIM-ENF [Antitrust Criminal Enforcement Division]." The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation." Then, "[t]he investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred."

81. As discussed above, the first indictments to result from the DOJ's investigation of the generic drug industry were filed in the Eastern District of Pennsylvania in December 2016 against former executives of Heritage Pharmaceuticals, Inc., Jeffrey A. Glazer and Jason T.

³² See *Antitrust Division Manual*, Chapter III, Section F.1 at III-82 (2015).

 $^{^{33}}$ *Id*.

³⁴ *Id.* at III-83.

 $^{^{35}}$ *Id.*

Malek. Glazer and Malek pleaded guilty to violating Section 1 of the Sherman Act in January 2017.

- 82. Further, as a result of the Connecticut Attorney General's two-year investigation of the generic drug industry, the AG Complaint was filed in December 2016 and provides additional details on anticompetitive conduct in certain generic drug markets. According to the AG Complaint, "[i]n July 2014, the State of Connecticut initiated a non-public investigation into suspicious price increases for certain generic pharmaceuticals. The information developed through that investigation, which is still ongoing, uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for a number of generic pharmaceuticals in the United States."
- 83. One of the targets of the DOJ investigation has reportedly applied for leniency. This is significant because the applicant must admit to participation in a criminal antitrust violation. As the DOJ notes on its web site:
 - 5. Does a leniency applicant have to admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter?

Yes. The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will receive no benefit from the leniency program.³⁷

³⁶ See AG Complaint at ¶ 1.

³⁷ Frequently Asked Questions Regarding the Antitrust Division's Leniency Program, Dept. of Justice (last visited Jan. 24, 2017), *available at* http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program.

- 84. The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials." 38
- 85. DOJ and state government investigations of Defendants' alleged price-fixing conduct in the generic pharmaceutical industry continue.

F. Order Denying Motion to Dismiss in Propranolol Antitrust Litigation

- 86. In another generic drug price-fixing case, *In re: Propranolol Antitrust Litigation*, the U.S. District Court for the Southern District of New York entered an Opinion and Order on April 6, 2017 denying a motion to dismiss direct purchasers' consolidated amended complaint. *See In re Propranolol Antitrust Litig.*, No. 16-cv-9901, -- F.3d --, 2017 WL 1287515 (S.D.N.Y. Apr. 6, 2017) (Rakoff, J.) ("Propranolol Order"). Plaintiffs in the *Propanolol* case alleged a conspiracy among generic manufacturers to manipulate the market for generic propranolol, with facts similar to those alleged herein for the generic Divalproex ER market. Defendants Mylan and Par are also named as defendants in the *Propanolol* case.
- 87. In denying the defendants' motion to dismiss, Judge Rakoff found that *Propranolol* plaintiffs pled a plausible price-fixing conspiracy and that plaintiffs alleged market specific factors suggesting that defendants had an incentive to manipulate prices. *See* Propranolol Order at 11, 13, 24. Judge Rakoff noted that Plaintiffs' pleadings "set forth in detail a regulatory regime that has historically pushed the price of Propranolol downwards and

³⁸ *Id*.

³⁹ The *Propranolol* defendants are Actavis Elizabeth, LLC, Teva Pharmaceuticals USA, Inc., Pliva, Inc., Mylan Inc., Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., Par Pharmaceutical, Inc., Heritage Pharmaceuticals Inc., Breckenridge Pharmaceutical, Inc., and Upsher-Smith Laboratories, Inc.

gradually reduced defendants' profits, thereby giving them a common motive to conspire." *Id.* at 13. Further, Judge Rakoff found that plaintiffs' pleadings "allege a pattern of price fixing spanning several years and no clear mechanism through which the defendants could legitimately and consistently monitor each other's pricing activity." *Id.* at 15-16.

- 88. The *Propranolol* plaintiffs alleged the presence of four plus factors to plausibly establish that the defendants conspired to fix prices of Propranolol capsules and tablets in 2013 and 2015: "(1) defendants had a motive to increase prices because they operate in an oligopolistic market characterized by falling prices; (2) the price increases were against defendants' self-interest because in a competitive market, defendants should have tried to undercut each other's prices to increase their market share; (3) defendants frequently communicated at trade association meetings; and (4) there are ongoing state and federal investigations for price manipulation of generic drugs, including Propranolol." *Id.* at 10-11, 24.
 - 89. As alleged herein, the same plus factors exist in the market for Divalproex ER.
- 90. Judge Rakoff rejected defendants' explanations for Propranolol price increases. For example, "plaintiffs plausibly allege that because the FDA did not report a shortage of Propranolol capsules following Mylan's exit, there was no 'shift' in the total supply of Propranolol that would rationally increase prices." *Id.* at 17. In addition, "while it is true that defendants' price increases did not always align on a monthly basis, defendants consistently raised prices on a <u>bi-monthly</u> and <u>quarterly</u> basis, which is consistent with an illegal agreement." *Id.* (emphasis in original). Similar price increases for Divalproex ER are shown in this complaint. *See infra*.

G. In re: Generic Pharmaceuticals Pricing Antitrust Litigation

- 91. On April 6, 2017, the U.S. Judicial Panel on Multidistrict Litigation entered a Transfer Order granting Rochester Drug Cooperative, Inc.'s motion to transfer ten generic drug price-fixing actions to the Eastern District of Pennsylvania for inclusion in *In re: Generic Digoxin and Doxycycline Antitrust Litigation*, MDL No. 2724 (E.D. Pa.). The MDL was renamed *In re: Generic Pharmaceuticals Pricing Antitrust Litigation* and now includes price-fixing allegations for eighteen generic drugs: (1) Doxycycline, (2) Digoxin, (3) Albuterol, (4) Clomipramine, (5) Desonide, (6) Pravastatin, (7) Divalproex, (8) Benazepril HCTZ, (9) Levothyroxine, (10) Propranolol, (11) Baclofen, (12) Glyburide, (13) Ursodiol, (14) Amitriptyline, (15) Lidocaine/Prilocaine, (16) Clobetasol, (17) Fluocinonide, and (18) Econazole.
- 92. This case has been filed as a related case to *In re Generic Pharmaceuticals*Pricing Antitrust Litigation, MDL No. 2724.

VII. THE GENERIC DRUG MARKET IS HIGHLY SUSCEPTIBLE TO COLLUSION

- 93. The factors necessary to show that a market is susceptible to collusion are present in this case:
 - (1) **High Degree of Industry Concentration** As discussed above, a small number of competitors control a significant market share for generic Divalproex ER. The Divalproex ER market is highly concentrated and dominated by Defendants.
 - (2) Barriers to Entry Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the generic drug market. Barriers to entry increase the market's susceptibility to a coordinated effort among the dominant entities in the generic drug industry to maintain supra-competitive prices.
 - (3) **Demand Inelasticity** Generic Divalproex ER is necessary treatment for millions of patients. Demand is inelastic if an increase in price results in a relatively small decline in demand for the product. Demand is inelastic for products such as Divalproex ER because consumers cannot readily substitute alternative products.

- (4) Lack of Substitutes Some patients are unable to substitute other medications for generic Divalproex ER. Generic Divalproex ER is a commonly prescribed anticonvulsant to treat seizures and migraines.
- (5) **High Degree of Interchangeability** Defendants' generic Divalproex ER products are interchangeable as they contain the same chemical compounds made from the same raw materials. Thus, generic Divalproex ER is standardized across suppliers and is highly interchangeable from one Defendant to the next.
- (6) **Absence of Competitive Sellers** Defendants have maintained supracompetitive pricing for generic Divalproex ER throughout the Class Period. Defendants have oligopolistic market power in the generic Divalproex ER market, which enables Defendants to increase prices without losing market share to non-conspirators.
- (7) Opportunities for Contact and Communication Among Competitors As discussed above, certain Defendants are members of trade association GPhA which provides and promotes opportunities to communicate.
- 94. Defendants' dominant market power has allowed them to substantially foreclose the market to rival competition, thereby impairing competition, maintaining and enhancing market power, and enabling Defendants to charge Plaintiff and the Class Members inflated prices above competitive levels for generic Divalproex ER.

VIII. CLASS ACTION ALLEGATIONS

95. Pursuant to Federal Rules of Civil Procedure 23(a), (b)(2) and (b)(3), Plaintiff brings this action on behalf of a class defined as follows:

All persons or entities that directly purchased generic Divalproex ER from Defendants in the United States and its territories and possessions at any time during the period June 2013 through the present (the "Class Period").

Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

96. Members of the Class are so numerous that joinder is impracticable. Plaintiff believes that there are hundreds of Class Members, geographically dispersed throughout the

United States such that joinder of all Class Members is impracticable. Further, the Class is readily identifiable from information and records maintained by Defendants

- 97. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff's interests are not antagonistic to the claims of the other Class members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.
- 98. Plaintiff will fairly and adequately protect and represent the interests of the Class.

 The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.
- 99. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law.
- 100. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby determining damages with respect to the Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.
- 101. The common legal and factual questions, which do not vary from Class member to Class member and which may be determined without reference to individual circumstances of any Class member, include, but are not limited to, the following:
 - (a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby artificially increase the prices of generic Divalproex ER in the United States;
 - (b) The duration and extent of the alleged contract, combination, or conspiracy;

- (c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;
- (d) The effect of the contract, combination, or conspiracy on the prices of generic Divalproex ER in the United States during the Class Period;
- (e) Whether Defendants' conduct caused supracompetitive prices for generic Divalproex ER;
- (f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiff and other members of the Class; and
- (g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.
- 102. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.
- 103. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

IX. INTERSTATE TRADE AND COMMERCE

104. During the Class Period, Defendants, directly or through one or more of their affiliates, sold Divalproex ER throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

- 105. The business activities of Defendants that are the subject of this action were within the flow of, and substantially affected, interstate trade and commerce.
- 106. Defendants' and their co-conspirators' conduct, including the marketing and sale of Divalproex ER, took place within, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.
- 107. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce as Defendants deprived Plaintiff of the benefits of free and open competition in the purchase of Divalproex ER within the United States.
- 108. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices of Divalproex ER, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Divalproex ER prices, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

X. DEFENDANTS' ANTITRUST VIOLATIONS

- 109. Defendants' combination and conspiracy had the following anticompetitive effects in the market for generic Divalproex ER:
 - (a) Competition in the market for generic Divalproex ER has been reduced;
 - (b) Prices for generic Divalproex ER have increased and have not followed the typical pricing patterns of generic drugs over time; and
 - (c) U.S. purchasers have been deprived of the benefit of price competition in the market for generic Divalproex ER.
- 110. During the Class Period, Plaintiff and Class Members directly purchased generic Divalproex ER from Defendants. As a result of the Defendants' anticompetitive conduct,

Plaintiff and Class Members paid more for generic Divalproex ER than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

- 111. Because Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiff and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such damages will be calculated after discovery and upon proof at trial.
- 112. Defendants' misconduct reduced competition in the generic Divalproex ER market, reduced choice for purchasers, and caused injury to purchasers.
- 113. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for generic Divalproex ER.

XI. CLAIM FOR RELIEF

VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

- 114. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.
- 115. Defendants and their co-conspirators entered into, and engaged in, a contract, combination, or conspiracy in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.
- 116. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

- 117. Defendants' anticompetitive acts were intentional, were directed at the sales of Divalproex ER in the United States, and had a substantial and foreseeable effect on interstate commerce by raising and fixing Divalproex ER prices throughout the United States.
- 118. In formulating and effectuating their combination or conspiracy, Defendants and their co-conspirators engaged in anticompetitive activities, the purpose and effect of which were to artificially fix, raise, maintain and/or stabilize the prices of generic Divalproex ER, including: (1) participating in meetings to discuss their respective generic drug products; (2) agreeing to coordinate and manipulate the prices and available supply of generic Divalproex ER in a manner that deprived purchasers in the U.S. of price competition; and (3) providing pretextual justifications to purchasers and the public to explain any raises, maintenance or stabilization of the prices for Defendants' generic Divalproex ER.
- 119. The contract, combination, or conspiracy had the following direct, substantial, and reasonably foreseeable effects upon commerce in the United States:
 - a. Prices charged to, and paid by, Plaintiff for Divalproex ER were artificially raised, fixed, maintained, or stabilized at supra-competitive levels;
 - b. Plaintiff was deprived of the benefits of free, open, and unrestricted competition in the sale of Divalproex ER in the United States market; and
 - c. Competition in establishing the prices paid for Divalproex ER was unlawfully restrained, suppressed, or eliminated.
- 120. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

- 121. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another on the pricing of generic Divalproex ER in the U.S. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.
- 122. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.
- 123. The conspiracy had its intended effect, as Defendants benefited from their collusion and the elimination of competition, both of which artificially inflated the prices of generic Divalproex ER, as described herein.
- 124. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for generic Divalproex ER than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.
- 125. Defendants' unlawful conduct as alleged herein poses a significant, continuing threat of antitrust injury for which injunctive relief is appropriate under Section 16 of the Clayton Act.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

A. Certification of the action as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;

B. Permanent injunctive relief that enjoins Defendants from violating the antitrust

laws and requires them to take affirmative steps to dissipate the effects of the violations;

C. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade

in violation of the Sherman Act, 15 U.S.C. § 1;

D. A judgment against Defendants, jointly and severally, for the damages sustained

by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other

monetary relief provided by applicable law, including treble damages;

E. By awarding Plaintiff and Class Members pre-judgment and post-judgment

interest as provided by law, and that such interest be awarded at the highest legal rate from and

after the date of service of the complaint in this action;

F. The costs of this suit, including reasonable attorney fees; and

G. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial,

pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

DATED: June 6, 2017

Respectfully submitted,

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